UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,314	10/01/2004	Sean Lilienfeld	JAB 1705	4828

27777 7590 08/07/2008

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,314	LILIENFELD ET AL.	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-8,10,12,13 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-8,10,12,13 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3,4,6-8, 10, 12, 13, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilkinson et al. in view of Yankner et al. (US Pat. 6,080,778) and WO 95/06470.

Wilkinson et al. disclose that 24 mg/day is the optimal galantamine hydrobromide dose for treatment of Alzheimer's disease (pages 854, 856, 857).

Yankner et al. disclose the administration of statins for treatment of Alzheimer's disease (Column 3, lines 20-53).

WO 95/06470 disclose that Alzheimer's disease is the most common type of dementia in the United States (Page 1, lines 23-24). A method of treating Alzheimer's disease with a HMG-Co A reductase inhibitor, such as lovastatin, simvastatin, pravastatin and fluvastatin is disclosed (Page 3, lines 25-35, Pages 4-8, Page 9, lines 1-31). It is disclosed that the doses may be varied, depending on the age, severity, body weight and other conditions of the human patients, that daily dosages for adults ranges from about 1 mg to 1000 mg, preferably 5 to 100 mg, and that higher doses may be favorable employed as required (Page 11, lines 11-16).

The prior art discloses the treatment of Alzheimer's disease with 24 mg/day of Galanthamine. The difference between the prior art and the claimed invention is that the prior

art does not expressly disclose the combination of Galanthamine and statins for treatment of Alzheimer's disease. However, the prior art amply suggests the same as the prior art disclose that both are effective for treatment of Alzheimer's disease. As such, one of ordinary skill in the art would have been motivated to combine the prior art with the expectation that the combination would be effective for treatment of Alzheimer's disease. Further, one of ordinary skill would have been motivated to use various amounts, including the amounts claimed, depending on the effectiveness of the treatment of Alzheimer's disease.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

Fulton et al is no longer part of the rejection herein, as such, the Applicant's arguments as to the same are moot. Wilkinson et al. specifically discloses that 24 mg/day is the optimal dose.

The Applicant presents the Declaration of Joan Amatniek as evidence of synergism. However, the evidence is not commensurate in scope with the claims. Claims 10, 12, 13, 19 are not limited to Alzheimer's dementia but encompass any type of dementia. The declaration only shows the use of 24 mg of galantamine and does not appear to indicate the dose of statin used. See *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at "elevated temperatures" using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d

1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims.).

Further, there is insufficient evidence to establish that there was a synergistic effect with respect to the combination of galantamine and statin; significantly, the original trials were not designed to ensure sufficient statistical power to asses the effect of statins, administration of statins was heterogenous with respect to specific statin, dose and treatment duration and follow up was limited to 5 to 6 months which may be insufficient for comparing effects of statins and galantmine (See Page 60 of Winblad et al. which is the evidence cited by the Declarant as supporting the conclusion of synergy). As such, it cannot be concluded from the data that the combination of galantamine and statin is synergistic much less synergistic over the entire scope of the claims which encompasses any statin and/or dose of statin.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner

maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
August 7, 2008

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616